About this article

I first met Brussels-based lawyer, An Vijverman, at the European Centre for Clinical Research Training Data Transparency Conference in February 2019. The conference brought together the clinical trials industry – sponsors and contract research organisations – regulators, watchdogs, and academics. There were sessions on regulatory aspects; how the data transparency rules are lived; proactive approaches to data transparency; anonymisation; and the future of data transparency. My colleague Tracy Farrow and I spoke about smart-authoring clinical study reports (CSRs) to reduce required effort with data sharing, using CORE Reference in the "proactive approaches" session. An spoke with authority grounded in her legal expertise, adding a new dimension to the "regulatory aspects" session. It was enlightening for me as a medical writer charged with writing CSRs that share data responsibly to hear about the legal aspects to enable me to apply the regulations as intended. An spoke about compliance with the EU Clinical Trials Regulation (CTR), Medical Devices Regulation, and General Data Protection Regulation (GDPR) and how these regulations all impact data transparency.

Hoping to take advantage of her legal brain, I asked An if informed consent forms (ICFs) need to reflect that the data gathered in clinical trials are disclosed through the publication of clinical documents such as CSRs in the EU, and if so how do ICF authors need to adapt standard ICF texts. An was able to explain this in non-legal jargon, that I found easy to navigate, and she kindly agreed to write this up and share it with readers of *Medical Writing* in the following article.

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Processing health-related data for scientific research: Is consent an appropriate legitimate ground?

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Is informed consent needed to process clinical trial data?

Since May 25, 2018, the GDPR[1] has come into application. This means – or should mean – a harmonisation of the rules on data processing throughout Europe. However, the European Member States continue to interpret certain aspects of data processing differently, such as the interpretation of legitimate grounds needed for processing health-related data for scientific research. Not all Member States are aligned as to whether the informed consent of the participant is required to process health-related personal data for scientific research purposes.

What does GDPR say?

Article 6 GDPR lays down the possible legitimate grounds for processing personal data in general. Article 9.1 GDPR further prohibits the processing of health-related data, except if one of the conditions laid down in Article 9.2 GDPR is fulfilled. When processing health-related personal data, the Controllers should ground their processing on one of the legitimate grounds laid down in Article 6 GDPR, as well as on one of the legitimate grounds laid down in Article 9.2 GDPR.

GDPR allows for processing of health-related data without informed consent being given

One of the legitimate grounds laid down in Article 6 GDPR and one of the conditions of Article 9.2 GDPR concerns the (explicit) consent of the data subject (Articles 6.1.a and 9.2.a GDPR). However, Articles 6.1 and 9.2 GDPR also contain other possible legitimate grounds that could be used for processing health-related personal data for scientific research purposes.

So, according to Article 6 GDPR, one could alternatively also justify the processing of personal data for scientific research purposes as the processing that would be necessary for the purposes of the legitimate interests pursued by the Controller (Article 6.1.f GDPR) or because the processing is necessary for the performance of a task carried out in the public interest (Article 6.1.e GDPR).

Furthermore, according to Article 9.2.j GDPR, one could then alternatively justify the processing of health-related personal data for scientific research purposes as the processing that would be necessary for scientific research purposes, provided Article 89 (1) GDPR is also respected and provided the processing is proportionate to the aim pursued; respects the essence of the right to data protection; and provides for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject (Article 9.2.j GDPR). This means that if the processing of health-related data is necessary for scientific research purposes and if all other conditions laid down in Article 9.2.j GDPR are complied with, the consent of the data subject (Article 9.2.a GDPR) will not be required.

Article 89 (1) GDPR further contains the obligation to minimise data when performing scientific research. This means that if scientific research can be performed based on data processing that does not permit or no longer permits the identification of data subjects, one should do so. In other words, data should as far as possible be pseudonymised or – if possible – anonymised when being used for scientific research.

Hence according to the GDPR, the processing

of health-related data for scientific research is possible, without disposing of the informed consent of the data subject, provided the data are as far as possible pseudonymised or anonymised and provided the principle of proportionality and the right to data protection and the fundamental rights and interests of the data subjects are complied with.

Informed consent is not even recommended

I would even go a step further and advise not to ask for informed consent from the data subject to cover the processing of his or her personal data for scientific research purposes, based on another legitimate ground: a consent is only valid if it has been freely given (Article 7 GDPR) and consent should not be regarded as freely given if the data subject does not have a genuine or free choice or is unable to refuse or withdraw consent without detriment (Consideration 42 GDPR). Also, in order to ensure that consent is freely given, consent should not provide a valid legal ground for processing personal data in a specific case where there is a clear imbalance between the data subject and the Controller, in particular where the Controller is a public authority and it is therefore unlikely that consent was freely given in all the circumstances of that specific situation (Consideration 43 GDPR). In the context of scientific research, this means that if a patient decides to participate in scientific research, he or she cannot really freely consent or not with the processing of his or her personal data for that scientific research. Indeed, participating in scientific research *ipso facto* also implies the processing of the data subject's health-related data for the purpose of that scientific research. One may therefore conclude that the consent the patient would give for the processing of his or her health-related data for the purpose of scientific research cannot be given freely (and would thus by definition be invalid). The patient moreover has a subordinate relationship towards the investigator and/or research institution which implies an imbalance of power also seriously complicating free consent.

What does the European Data Protection Board say?

This reasoning has been confirmed by the European Data Protection Board in Opinion 3/2019[2] (Art. 70.1.b).

Legal opinion and advice to the authors of ICFs

I therefore conclude that it is not advisable to use consent as the legitimate ground for processing health-related personal data as this entails the risk that the freely given character of the consent is subject to discussion afterwards, in which case the data cannot (any longer) be processed legitimately. It is better to use instead the legitimate grounds of the necessity for the legitimate interests of the Data Controller/the necessity for performing a task carried out in the public interest (Article 6.1.f or e GDPR) and the necessity for scientific research purposes (Article 9.2.h GDPR).

To avoid any misunderstanding, I confirm that this reasoning is limited to the processing of personal data as part of scientific research but does not in any way influence the rules on performing the scientific research itself. Indeed, the rules on performing scientific research itself – requiring in most cases the informed consent of the participant as to his or her participation in the trial – continue to apply. It essentially concerns the rules laid down in the European Directive 2001/20//EC of the European Parliament and of the Council of April 4, 2001, on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use and in European Regulation (EU) 536/2014 of the European Parliament and of the Council of April 16, 2014, on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC – the latter is expected to come into application during 2020.

References

1. Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
2. Opinion 3/2019 of the European Data Protection Board of 23 January 2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR).